



Billing Code 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent Commercialization License: Method of Treating Periodontal Disease via ENPP1 Inhibition

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Arthritis and Musculoskeletal and Skin Diseases, of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent commercialization license to Petragen, Inc., a start-up company incorporated in the state of Delaware, to practice the inventions covered by the patent estate listed in the Supplementary Information section of this notice. This notice is intended to apprise the public of the aforementioned license and provide a fifteen (15) day notice period for the objection.

DATES: Only written comments and/or applications for a license which are received by the National Heart, Lung, and Blood Institute Office of Technology Transfer and Development on or before **[INSERT DATE 15 DAYS FROM DATE OF**

PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of patent applications (electronic only), inquiries, and comments relating to the contemplated an exclusive patent license should be emailed to: Benfeard Williams, II, Ph.D., Technology Transfer Manager, 31 Center Drive, Room 4A29, MSC 2479, Bethesda, MD 20892-2479, phone number 301-435-4507, or benfeard.williams@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property (Patent Estate)

HHS Ref. No. E-024-2018-0, U.S. Provisional Patent Application 62/590,824 filed November 27, 2017, International Patent Application PCT/US2018/062593 filed November 27, 2018, Chinese Patent Application 201880076753.7 filed November 27, 2018, European Patent Application 18816451.1 filed November 27, 2018, Israeli Patent Application 274529 filed November 27, 2018 and U.S. Patent Application 16/765,420 filed May 19, 2020, and any and all continuation or divisional applications claiming priority to any of the above.

The patent rights in these inventions have been assigned or exclusively licensed to the Government of the United States of America.

The aforementioned patent estate covers methods of treating or preventing periodontal disease in a subject by administering an inhibitor of ENPP1. In addition, the claims cover pharmaceutical compositions for use in the treatment or prevention of periodontal disease, or for increasing cementum formation. In particular, the dependent claims cover ENPP1 inhibitors comprising analogues of ATP derivatives, wherein the ENPP1 inhibitor is bound to nanoparticles, nanofibers, suture materials, microspheres, polymers, fibers, matrices, gels, or a combination thereof. The treatment methods also include dependent claims wherein treating or preventing periodontal disease comprises increasing cementum formation and wherein the composition is formulated for injection in gum tissue, local delivery at a surgical flap, buccal delivery, delivery by a resorbable suture, delivery by a wound healing dressing, or a combination of the foregoing.

Inhibition of the glycoprotein ENPP1 promotes cementum formation in mammals. Cementum, an avascular mineralized tooth root structure, attaches the tooth to the periodontal ligament and supporting bone. Cementum has limited turnover and subjects with periodontal disease experience localized loss of cementum resulting in the detachment of the periodontal ligament from the tooth root. Increasing cementum formation can be used to treat periodontal disease.

The prospective exclusive license territory may be worldwide and in a field of use that may be limited to *Therapeutics for periodontitis or gingivitis*, and where the “Licensed Products” are expected to be inhibitors of ecto-nucleotide pyrophosphate/phosphodiesterase-I (ENPP1) within the scope of the Licensed Patent Rights.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive patent commercialization license will be royalty bearing. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Heart, Lung, and Blood Institute Office of Technology Transfer and Development receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this notice will be presumed to contain business confidential information and any release of information in these license

applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: September 17, 2020.

Bruce D. Goldstein,

Director, Office of Technology Transfer and Development,

National Heart, Lung, and Blood Institute.

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